Erivedge®▼(vismodegib) Verification of Counselling Form	Initials
WARNING: EMBRYO-FOETAL DEATH AND SEVERE BIRTH DEFECTS Erivedge may cause embryo-foetal death or severe birth defects when administered to a pregnant woman. Hedgehog pathway inhibitors such as Erivedge have been demonstrated to be embryotoxic and/or teratogenic in multiple animal species and can cause severe malformations, including craniofacial anomalies, midline defects and limb defects. Erivedge must not be used during pregnancy.	
For All Patients	
I understand that:	
• Erivedge may cause serious birth defects and can cause the death of an unborn child	
• I must not share Erivedge with anyone. Erivedge is only prescribed for me	
• I must keep Erivedge out of the sight and reach of children	
• I must not donate blood while taking Erivedge and for 24 months after the last dose	
• I must return the unused capsules to my pharmacist or healthcare professional at the end of the treatment	
For Women Who Could Become Pregnant	
I understand that:	
• I must not take Erivedge if I am pregnant or plan to become pregnant	
• I must not become pregnant while taking Erivedge and for 24 months after my final dose	
• My healthcare professional talked with me about recommended forms of birth control: – Whilst I am taking Erivedge and for 24 months after my final dose, I must use 2 recommended forms of birth control at the same time unless I commit to not having sexual intercourse (abstinence)	
• I must have a negative pregnancy test conducted by my healthcare professional within a maximum of 7 days (day of pregnancy test = day 1) before starting Erivedge and each month during treatment	
• I must talk to my healthcare professional immediately during treatment and for 24 months after my last dose: – If I become pregnant or think for any reason that I may be pregnant – If I miss my expected menstrual period – If I stop using birth control – If I need to change my birth control during treatment	
• In case of pregnancy during treatment with Erivedge, I must stop treatment immediately	
• I must not breast-feed while I am taking Erivedge and for 24 months after my last dose	
• My healthcare professional will report any pregnancy to Roche, the maker of Erivedge	
For Male Patients	
I understand that:	
• I must always use a condom when having sex with a woman while I take Erivedge and for 2 months after my last dose, even if I have had a vasectomy. It is also important that my female partner uses contraception to avoid pregnancy	
• I will tell my healthcare professional if my female sexual partner becomes pregnant while I am taking Erivedge or within 2 months after my last dose	
• I should not donate semen at any time during treatment and for 2 months after my final dose of this medicine	
Report Pregnancy and Adverse Events to Roche on +44 (0)1707 367554	

Patient gender *(circle one):*	**Age:**	**Woman of childbearing potential** *(circle one):*
Male Female	_____ years	Yes No

Pre-treatment pregnancy test results *(circle one):*	**Date of the pre-treatment pregnancy test:**
Positive Negative	_____/_____/_____

Patient Confirmation

My doctor has reviewed with me the risks to an unborn baby or infant if they are exposed to Erivedge during pregnancy or breast-feeding. He/she has answered any questions I may have about these risks, and how to prevent them.

Patient Name (please print): _____

Patient Signature: _____

Date: _____

Prescriber Confirmation

I have explained to the patient named _____ (or the parent or guardian if the patient is mentally challenged) the risks of the treatment associated with Erivedge, including the risk of exposure to the unborn baby and/or infant during pregnancy and breast-feeding. I have asked the patient (or the parent or guardian if the patient is mentally challenged) if she/he has any questions regarding treatment and have answered those questions to the best of my ability.

Prescriber Name (please print): _____

Prescriber Signature: _____

Date: _____

PLEASE RETAIN THE ORIGINAL SIGNED DOCUMENT AND PROVIDE A COPY TO THE PATIENT

Prescribers must confirm completion of this Verification of Counselling Form for all new patients taking Erivedge via the healthcare professional web portal **www.erivedge-ppp.com.mt**

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Reporting forms and information can be found at www.medicinesauthority.gov.mt/adrportal. Adverse events should also be reported to Roche Products Ltd. Please contact Roche Drug Safety Centre by emailing welwyn.uk_dsc@roche.com or calling +44 (0)1707 367554.

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